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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Ho *et al.*

Serial No.: 10/652,813

Filed: August 29, 2003

Attorney Docket No.: 03-40155-US

TITLE: BENZOTROPOLONE
DERIVATIVES AND MODULATION OF
INFLAMMATORY RESPONSE

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97(c)

Commissioner for Patents
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Sir:

The above-identified Applicant submits herewith a copy of references, which may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 C.F.R. § 1.56. Form PTO-1449, attached hereto, lists references of which Applicant is aware, and which may be material to the examination of this application.

While the information cited in this Information Disclosure Statement may be "material" pursuant to 37 C.F.R. § 1.56, the filing of this reference should not be construed to be an admission that any patent, publication or other information referred to herein is, or is considered to be, either "prior art" for this invention or otherwise material to the patentability of this invention as defined in 37 C.F.R. § 1.56(b).

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It is believed that this Information Disclosure Statement is being filed prior to the mailing date of any final action, a notice of allowance, or an action that otherwise closes prosecution of the application pursuant to 37 C.F.R. §1.97(c)(2).

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Respectfully submitted,


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SUBSTITUTE FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE		ATTY. DOCKET NO. 03-40155-US	SERIAL NO. 10/652,813
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U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)
	AA	6,524,630 B2	02/25/2003	Schmitz			
	AB	6,491,943 B2	12/10/2002	Tsuji et al.			
	AC	6,348,224 B1	02/19/2002	Patil et al.			
	AD	5,861,415	01/19/1999	Majeed et al.			
	AE	6,113,965	09/05/2000	Goodsall et al.			
	AF	5,998,437	12/07/1999	Nishi et al.			
	AG	6,469,053 B1	10/22/2002	Romanczyk, Jr. et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	— NO
	BA	WO 01/21137 A1	03/29/2001	PCT		:		

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

CA	Araujo et al., Biological Activities of <i>Curcuma longa</i> L., Mem Inst Oswaldo Cruz, Rio de Janeiro, vol. 96, no. 5, July 2001, pp. 723-728.
CB	Hiipakka et al., Structure-activity relationships for inhibitions of human 5 α -reductases by polyphenols, Biochemical Pharmacology, vol. 63, 2002, pp. 1165-1176.
CD	Marnett et al., COX-2: A Target for Colon Cancer Prevention, Annu. Rev. Pharmacol. Toxicol., vol. 42, 2002, pp. 55-80.
CE	Acker, S.A.B.E.V.; Berg, D.J.V.D.; Tromp, M.N.J.L.; Griffioen, D. H.; Bennekom, W.P.V.; Der Vijgh, W.J.F.V.; Bast, A. Structural aspects of antioxidant activity of flavonoids. Free Radical Biol. Med. 1996, 20, 331-342.
CF	Balentine, D. A.; Wiseman, S.A.; Bouwens, L.C.M. The chemistry of tea flavonoids, Critical Reviews in Food Science and Nutrition. 1997, 37, 693-704.
CG	Berkowitz, J.E.; Coggon, P; Sanderson, G.W. Formation of epicatechins and its transformation to thearubigins during tea fermentation. Phytochemistry. 1971, 10, 2271-2278.
CH	Bryce, T.; Collier, P.D.; Fowlis, I.; Thomas, P.E.; Frost, D.; Wilkins, C.K. The structures of the theaflavins of black tea. Tetrahedron letters. 1970, 32, 2789-2792.
CI	Cao, G.; Alessio, H.M.; Cutler, R.G. Oxygen-radical absorbance capacity assay for antioxidants, Free Radical Biol. Med. 1993, 14, 303-311.
CJ	Coxon, D.T.; Holmes, A.; Ollis, W.D. Isotheaflavin. A new black tea pigment. Tetrahedron letters. 1970, 60, 5241-5246.
CK	Coxon, D. T.; Holmes, A.; Ollis, W.D.; Vora, V.C. The constitution and configuration of the theaflavin pigments of black tea, Tetrahedron letters. 1970, 60, 5237-5240.

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

CL	Collier, P.D.; Mallows, B.R.; Thomas, P.E.; Frost, D.J.; Korver, O.; Wilkins, C.K. The theaflavins of black tea. Tetrahedron. 1973, 29, 125-142.
CM	Galati, G.; Teng, S.; Moridani, M.Y.; Chan, T.S.; O'Brien, P.J. Cancer chemoprevention and apoptosis mechanisms induced by dietary polyphenolics. Drug metabolism and Drug interaction. 2000, 17, 311-349.
CN	Guo, Q.; Zhao, B.; Shen, S.; Hou, J.; Hu, J.; Xin, W. ESR study on the structure-antioxidant activity relationship of tea catechins and their epimers. Biochimica et Biophysica Acta. 1999, 1427, 13-23.
CO	Halder, J.; Tamuli, P; Bhaduri, A.N. Isolation and characterization of polyphenol oxidase from indian tea leaf (Camellia Sinensis). Nutritional Biochemistry. 1998, 9, 75-80.
CP	Halder, J.; Bhaduri, A. N. Protective role of black tea against oxidative damage of human red blood cells, Biochemical and Biophysical Research Communications. 1998, 244, 903-907.
CQ	Jovanovic, S.V.; Hara, Y.; Steenken, S.; Simic, M. Antioxidant potential of theaflavins. A pulse radiolysis study. J. Am. Chem. Soc. 1997, 119, 5337-5343.
CR	Katiyar, S.K.; Mukhtar, H. Tea antioxidants in cancer chemoprevention. Journal of cellular biochemistry supplement. 1997, 27, 59-67.
CS	Kondo, K.; Kurihara, M.; Fukuwara, K. Mechanism of antioxidant effects of catechins. Methods of Enzymology. 2001, 335, 203-217.
CT	Kuroda, Y.; Hara, Y. Antimutagenic and anticarcinogenic activity of tea polyphenols. Mutation Research, 1999, 436, 69-97.
CU	Leung, L.K.; Su, Y.; Chen, R.; Zhang, Z.; Huang, Y.; Chen, Z.Y. Theaflavins in black tea and catechins in green tea are equally effective antioxidants. American Society for Nutritional Sciences. 2001, 2248-2251.
CV	Lewis, J.R.; Davis, A.L.; Cai, Y.; Davies, A.P.; Wilkins, J.P.G.; Pennington M. Theaflavate B, Isotheaflavin-3'-O-gallate, neotheaflavin-3-O-gallate: three polyphenolic pigments from black tea. Phytochemistry. 1998, 49, 2511-2519.

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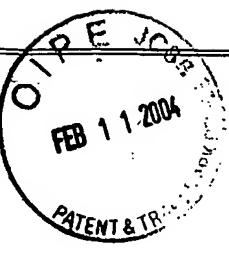
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CW	Lin, Y.L.; Tasi, S.H.; Lin-Shiau, S.Y.; Ho, C.T.; Lin, J.K. Theaflavin-3,3'-digallate from black tea blocks the nitric oxide synthase by down-regulating the activation of NF- κ B in macrophages. European Journal of Pharmacology. 1999, 367, 379-388.
CX	Miller, N.J.; Castelluccio, C.; Tijburg, L.; Rice-Evans, C. The antioxidant properties of theaflavins and their gallate esters-radical scavengers or metal chelators? FEBS letters. 1996, 392, 40-44.
CY	Nonaka, G.I.; Hashimoto, F; Nishioka, I. Tannins and related compounds. XXXVI. Isolation and structures of theaflagallins, new red pigments from black tea. Chem. Pharm. Bull. 1986, 34, 61-65.
CZ	Obanda, M.; Owuro, P O.; Mang'oka, R. Changes in the chemical and sensory quality parameters of black tea due to variation of fermentation time and temperature. Food Chemistry. 2001, 75, 395-404.
DA	Ou, B.; Hampsch-Woodill, M.; Prior, R.L. Development and validation of an improved oxygen radical absorbance capacity assay using fluorescein as the fluorescent probe. J. Agric. Food Chem. 2001, 49, 4619-4626.
DB	Robertson A. Effects of physical and chemical conditions on the in vitro oxidation of tea leaf catechins. Phytochemistry. 1983, 22, 889-896.
DC	Robertson A. The chemistry and biochemistry of black tea production - the non-volatiles. Instant Tea, Cultivation to Consumption, Chapman & Hall: London, UK. 1992, 555-601.
DD	Roberts, E.A.H.; Cartwright, R.A.; Oldschool, M. The phenolic substances of manufactured tea. I.-fractionation and paper chromatography of water-soluble substances. J. Sci. Food Agric. 1957, 8, 72-80.
DE	Sarkar, A.; Bhaduri, A. Black tea is a powerful chemopreventor of reactive oxygen and nitrogen species : comparison with its individual catechin constituents and green tea. Biochemical and Biophysical Research Communication. 2001, 284, 173-178.
DF	Shiraki, M.; Hara, Y.; Osawa, T.; Kumon, H.; Nakayama, T.; Kawakishi, S. Antioxidative and antimutagenic effects of theaflavins from black tea. Mutat. Res. 1994, 323, 29-34.

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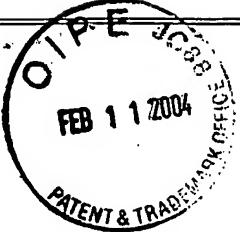
		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	— NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

DG	Subramanian, N.; Venkatesh, P; Ganguli, S.; Sinkar, V. P. Role of polyphenol oxidase and peroxidase in the generation of black tea theaflavins. J. Agric. Food Chem. 1999, 47, 2571-2578.
DH	Takino, Y.; Imagawa, H.; Horikawa, H.; Tanaka, A. Studies on the mechanism of the oxidation of tea leaf catechins - formation of the reddish orange pigment and its spectral relationship to some benzotropolone derivatives. Agricultural and Biological Chemistry. 1964, 28, 64-71.
DI	Tanaka, T.; Inoue, K.; Betsumiya, Y; Mine, C.; Kouno, I. Two types of oxidative dimerization of the black tea polyphenol theaflavin. J. Agric. Food Chem. 2001, 49, 5785-5789.
DJ	Tanaka, T.; Mine, C.; Inoue, K.; Matsuda, M.; Kouno, I. Synthesis of theaflavin from epicatechin and epigallocatechin by plant homogenates and role of epicatechin quinone in the synthesis and degradation of theaflavin. J. Agric. Food Chem. 2002, 50, 2142-2148.
DK	Valcic, S.; Muders, A.; Jacobsen, N. E.; Liebler, D.C.; Timmermann, B.N. Antioxidant chemistry of green tea catechins. Identification of products of the reaction of (-)-epigallocatechin gallate with peroxy radicals. Chem. Res. Toxicol. 1999, 12, 382-386.
DL	Wan, X.; Nursten, H. E.; Cai, Y; Davis, A.L.; Wilkins, J.P. G.; Davis, A.P. A new type of tea pigment-from the chemical oxidation of epicatechin gallate and isolated from tea. J. Sci. Food Agric. 1997, 74, 401-408.
DM	Wiseman, S.A.; Balentine, D.A.; Frei, B., Antioxidants in tea, Critical Reviews in Food Science and Nutrition, 1997, 37, 705-718
DN	Yang, C.S.; Chung, J. Y; Yang., G.Y.; Chhabra, S.K.; Lee, M.J. Tea and tea polyphenols in cancer prevention. J. Nutr. 2000, 130, 472-478.
DO	Yoshida, H.; Ishikawa, T.; Hosoi, H.; Suzukawa, M.; Ayaori, M.; Hisada, T.; Sawada, S.; Yonemura, A.; Higashi, K.; Ito, T.; Nakajima, K.; Yamashita, T.; Tomiyasu, K.; Nishiwaki, M.; Ohsuzu, F.; Nakamura, H. Inhibitory effects of tea flavonoids on the ability of cells to oxidize low density lipoprotein. Biochemical Pharmacology. 1999, 58, 1695-1703

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DP	Delgado, J. N. And W. A. Remers 1998. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry, Lippincott Williams & Wilkins Publishers.
DQ	Huang, M-T et al., Inhibitory effect of black tea constituents on 12-O-tetradecanoylphorbol-13-acetate induced inflammation, pro-inflammatory cytokine expression and arachidonic acid metabolism, for Cancer Research and Center for Advanced Food Technology, Rutgers University, Proceedings of the American Association for Cancer Research, vol. 44, 2003.
DR	Vinson, Black and greet tea and heart disease: A review, 2000, Biofactors 13, 127-132.
DS	Weisburger et al., Mechanisms of chronic disease causation by nutritional factors and tobacco products and their prevention by tea polyphenols, 2002, Food & Chemical Toxicology, 40, 1145-1154.
DT	Yang et al., Black tea constituents, theaflavins, inhibit 4-(methylnitrosamino)- 1-(3-pyridyl)-1-butanone (NNK)-induced lung tumorigenesis in A/J mice, 1997, Carcinogenesis, 18, 2361-2365.
DU	Liang et al., Inhibition of 12-O-Tetradecanoylphorbol-13-Acetate-Induced Inflammatory Skin Edema and Ornithine Decarboxylase Activity by Theaflavin-3,3'-Digallate in Mouse, 2002, Nutrition and Cancer, 42 (2), 217-223.
DV	Sala et al., Assessment of the anti-inflammatory activity and free radical scavenger activity of tiliroside, 2003, European Journal of Pharmacology 461(1), 53-61.
DW	Ukiya et al., Constituents of Compositae Plants. 2. Triterpene Diols, Triols, and Their 3-O-Fatty Acid Esters from Edible Chrysanthemum Flower Extract and Their Anti-inflammatory Effects, 2001, Journal of Agricultural and Food Chemistry 49(7), 3187-3197.
DX	Huang et al., 2003, Protective effect of dibenzolmethane on chemically-and UV light-induced skin, inflammation, sunburn lesions, and skin carcinogenesis in mice, In: Food Factors in Health Promotion and Disease Prevention, Washington DC, American Chemical Society: 196-207.
DY	Huang et al., Inhibitory Effect of Curcumin, Chlorgenic Acid, Caffeic Acid, and Ferulic Acid on Tumor Promotion in Mouse Skin by 12-O-Tetradecanoylphorbol-13-acetate, 1988, Cancer Research, 48, 5941-5946.

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